REMARKS/ARGUMENTS

Entry of the foregoing and favorable reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.116, and in light of the remarks which follow, are respectfully requested. This amendment is in response to the final Official Action mailed on February 17, 2010. Claims 61 and 91 have been amended and claims 62, 70-72, 76, 77, 82, 84, and 85 are pending. Support for the "neosynthesis" limitation can be found at pages 24, 33, and 36-37 of the pending application. No new matter has been added by way of these amendments.

The Examiner has rejected the pending claims under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. (*Office Action,* pages 2-3.) Specifically, the Examiner believes that the metes and bounds of claims 61 and 91 are vague and indefinite with regard to the enumerated skin conditions. (*Id.*) "In rejecting a claim under the second paragraph of 35 U.S.C. § 112, it is incumbent on the Examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims." *Ex parte Wu*, 10 U.S.P.Q.2d 2031 (B.P.A.I., 1989) citing *In re Moore,* 439 F.2d 1232 (C.C.P.A., 1971). While Applicants respectfully submit that one skilled in the art would understand the skin conditions contemplated by the claimed invention, to expedite prosecution, Applicants have amended the claims to provide further clarification and remove any alleged ambiguities. Accordingly, this rejection is rendered moot and should be withdrawn.

The Examiner has also rejected the claims under 35 U.S.C. § 103(a) as allegedly being unpatentable over a combination of no less than five references including *Loden*, *Sekimoto*, *Milkova*, *Alonzo*, and *Brun*. The Examiner believes that *Loden* teaches all of the elements of the claimed invention, but does not "specifically teach that skin lipids of either cholesterol or ceramide (ceramide 1 or ceramide 2) increases after administration of the oil." (*Office Action*, page 5.) Then, the Examiner states that the combined teachings of *Loden* and *Sekimoto* "teach the instantly claim invention except for administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of sunflower oil and unsaponifiable material from sunflower oil." (*Office Action*, page 7.) Thus, it appears from the Examiner's own admission that at least two elements are missing from *Loden*, and/or the combination of *Loden* and *Sekimoto*. The Examiner relies on three other secondary references which allegedly teach what is missing from *Loden* and/or *Sekimoto*.

In this case, it appears that all the Patent Office has done was find individual elements of the claimed invention in discrete prior art references and, using only Applicants' claims and disclosure as a guide, contend that the disclosures, if combined, would produce the claimed invention. Indeed, the Patent Office would appreciate that half of the elements required by the claimed invention are missing from *Loden*. There is no reason, apart from the retrospective view of using Applicants' application as a road map, to select the element of adding "at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil" (hereinafter "sunflower distillates"). Indeed, all the Patent Office has done was find various components of vegetable oils (sterols) in the prior art

and alleged that these individual components could be substituted for sunflower distillates. And, as detailed herein, these secondary references simply provide no disclosure of biological uses of plant oils or their components, only their isolation and structural elucidation. Such a hindsight construction is not permitted and does not constitute a *prima facie* case of obviousness and, for this reason alone, the rejection must be withdrawn.

Applicants submit that even if rationale existed by which to combine the collective teachings of the cited references, the combination would not result in the claimed invention. *Loden* describes tests to determine whether certain oils have any beneficial affect on skin subjected to sodium-laurel-sulfate. Of the different oils tested, *Loden* discloses that only canola-oil "reduced the degree of irritation compared with water." (*Loden*, page 219) No mention is made in *Loden* of testing "oil distillates of sunflower oil and unsaponifiable materials from sunflower oil" as in the claimed invention. Nor is there any disclosure that the canola-oil of *Loden* may be applied to treat skin conditions including sensitive skin, dry skin, pruritus, ichtyosis, acne, xerosis, atopic dermatitis, cutaneous desquamation, skin subjected to actinic radiation, or skin subjected to ultraviolet radiation.

Moreover, *Loden* does not teach that application of any oil induces neosynthesis resulting in an increase in the quantity of skin lipids, let alone an increase in the quantities of any of cholesterol, ceramide 1, and/or ceramide 2. In fact, the Patent Office concedes that "Loden does not specially teach that skin lipids…increase after administration of the oil." (*Office Action*, page 5). Rather, *Loden* suggests that application of canola-oils merely supplies lipids to damaged skin. (*Loden, page 219*) In fact, *Loden* reports that studies have shown that "topically applied lipids may [even] interfere

with the lipid synthetic activity of the skin." (*Id.*) In view of the disclosures of *Loden*, one of ordinary skill would not contemplate administering an oil to the skin to increase the quantities of skin lipids or to induce their neosynthesis. Rather, from such a teaching away the skilled artisan would expect the opposite, namely that administration would decrease neosynthesis.

Applicants have conducted experiments which show, surprisingly, that the claimed invention significantly increases neosynthesis of skin lipids when compared to controls. (*Application,* page 24.) In fact, the neosynthesis of ceramides is higher after treatment with sunflower distillate/unsaponitable material than after treatment with epidermal growth factor or with lactic acid, which are both known to stimulate synthesis of ceramides in the skin. *(Id.)* Applicants have also conducted clinical studies to evaluate the effect of a cosmetic composition comprising the designated ingredients. (*Id.* at page 33.) The results of these studies indicate a "statistically significant increase in the level of surface skin lipids" relative to controls. (*Id.* at pages 36-37.) Clearly, this is not the result expected by *Loden*.

None of the secondary references cure the deficiencies of *Loden, i.e.* they don't disclose (1) administering a composition comprising an oil distillate of sunflower oil or unsaponifiable materials from sunflower oil, or (2) increasing the quantity of skin lipids by neosynthesis. *Sekimoto* describes a preparation comprised of sitosterol or a sitosterol-containing vegetable oil. *Sekimoto* discloses that this preparation is used to prevent drying and keratinization of plantar skin (*e.g.* callused skin on the sole of a foot). (*Sekimoto,* page 1.) Moreover, the reference discloses that "GLC analysis of the fluid secreted from the sole of a foot showed that it contained

cholesterol, sitosterol, and triterpene alcohols." (*Id.*) Only the content of sitosterol in this sample was found to be higher than that normally found in blood. (*Id.*) *Sekimoto* does not disclose that administration of the preparation increases the quantities of cholesterol, ceramide 1 and/or ceramide 2 in the skin, as in the claimed invention. Moreover, *Sekimoto* is limited merely to treating plantar skin, and hence is directed to a completely different problem than the skin conditions of the claimed invention.

Milkova and *Alonso* are directed to the isolation and structural elucidation of oils found in vegetable matter. Specifically, *Milkova* is directed to the isolation of certain sterols by preparative TLC and their subsequent hydrolysis to produce steroid dienes and disteroid ethers. (*Milkova,* page 1.) Similarly, *Alonso* is directed to "the application of a [gas chromatography] procedure for rapid analysis of the total sterol fraction of vegetable oils, milk, fat, or mixtures [thereof], to detect any admixture of sunflower or olive oil and any addition of vegetable oils to milk fat." (*Alonso*, Abstract.) Clearly, these references never contemplate the biological properties of sterols or their potential application to treat the skin conditions of the claimed invention. Nor does either reference teach that administration of an oil or unsaponifiable material increases the quantity of any skin lipids or induces their neosynthesis. Such teachings are completely missing from these references.

Brun discloses a cosmetic oil composition for use in cosmetics comprising a mixture of jojoba oil, sunflower seed oil, and at least one unsaponifiable fraction of a vegetable oil (*e.g.* soya, avocado, maize or sunflower oil). (*Brun,* col.2 ll.87-92.) *Brun* discloses that these compositions maintain the water content of the skin by preventing water from evaporating and, thus are useful for improving the appearance of

senile, dry or rough skin. (*Id.* at col.2. ll.71-75.) Like *Sekimoto*, *Milkova*, and *Alonso*, *Brun* does not disclose that administration of a composition comprising a plant oil increases the quantity of cholesterol, ceramide 1, or ceramide 2, let alone is useful in treating the claimed skin conditions. Accordingly, there is no disclosure in the cited art that administration of distillates or unsaponifiable materials from sunflower oil induces neosynthesis of ceramides or cholesterol, increasing their quantities, for treatment of the claimed skin conditions. Therefore, even if *Loden* were combined with *Sekimoto*, *Milkova*, *Alonso*, and *Brun*, such a combination would not result in the claimed invention. This rejection should be withdrawn.

Finally, there is no disclosure in any of the secondary references that any specific sterol found in any vegetable oil can be used as a substitute for sunflower distillates. There clearly is no teaching that any specific sterol component isolated in *Milkova*, *Alonso*, or *Brun* could be substituted for the components of the claimed invention with any reasonable expectation of success in treating the claimed skin conditions, and certainly no indication that the administration of any single component would lead to an increase in skin lipid quantities. Even after *KSR v. Teleflex*, 550 U.S. 398, 402 (2007), it is not enough that certain additional steps could be done. There must be some reason to suppose that they would be done and nothing in *Loden* leads to that conclusion. *See also United States v. Adams*, 383 U.S. 39, 50-52 (1965) (where the Court held that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be non-obvious). In this case, the secondary references provide no further reason to make the combination or substitution proposed by the Examiner. Applicants respectfully request that this rejection be

withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: July 16, 2010

Respectfully submitted,

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